

THE LANCET

Psychiatry

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed.
We post it as supplied by the authors.

Supplement to: Gilbody S, Peckham E, Bailey D, et al. Smoking cessation for people with severe mental illness (SCIMITAR+): a pragmatic randomised controlled trial. *Lancet Psychiatry* 2019; published online April 8. [http://dx.doi.org/10.1016/S2215-0366\(19\)30047-1](http://dx.doi.org/10.1016/S2215-0366(19)30047-1).

Statistical appendix

Primary analysis

The primary outcome of CO-verified smoking cessation at 12 months was intended to be analysed via a mixed-effect logistic regression model to compare the bespoke smoking cessation service intervention with usual care. Indeed, this was as planned in the pre-specified statistical analysis plan. The model was to include CO-verified smoking status at six and 12 months (repeated measures within participant) and be adjusted for baseline smoking severity (self-reported number of cigarettes smoked per day), time, treatment group and a treatment group-by-time interaction, with site as a random effect. Participant, nested within site, was also to be treated as a random effect to account for the repeated measures within subject. However, this model failed to converge. Therefore, separate multi-level logistic regression models were run to compare the outcome at month six and at month 12, i.e. two models, instead of one model which incorporates the repeated measurements. The two models were each adjusted for baseline smoking severity, with site as a random effect. The odds ratio (OR), corresponding two-sided 95% confidence interval (CI) and p-value for the treatment effect at months six and 12 are presented. The treatment effect at month 12 serves as the primary end point, and the effect at month six as a secondary end point.

Sensitivity analyses

Post-hoc GEE analysis

Given that the pre-specified repeated measures mixed logistic regression primary analysis model did not converge, post-hoc sensitivity analyses were conducted using GEE (generalized estimating equations) techniques. This allowed for the repeated measures within participants to be accounted for, but the multilevel nature of the data (i.e. participants within site) cannot be controlled for in the same way as including a random effect for site in the mixed logistic regression. Two GEE models were run: i) one controlling for baseline smoking severity, and including an interaction between allocation and time; and ii) one controlling for both baseline smoking severity and site as covariates, and including an interaction between allocation and time. Both specified a binomial family and logit link, with an exchangeable correlation structure.

Post-hoc GEE analysis results

Using GEE to account for the repeated measures, the OR adjusting for baseline number of cigarettes smoked is 2.3 (95% CI 1.2 to 4.5, $p=0.01$) at six months and 1.6 (95% CI 0.9 to 2.8, $p=0.12$) at 12 months. When the GEE model was additionally adjusted for site, the treatment effects were estimated at an OR of 2.5 (95% CI 1.3 to 4.8, $p=0.01$) at six months and 1.6 (95% CI 0.9 to 2.9, $p=0.12$) at 12 months.

Systematic review search term appendix

1. exp Clinical Trial/
2. exp Randomized Controlled Trial/
3. exp Double-Blind Method/
4. exp Single-Blind Method/
5. exp Cross-Over Studies/
6. randomized controlled trial.pt.
7. clinical trial.pt.
8. controlled clinical trial.pt.
9. (clinic\$ adj2 trial).mp.
10. (random\$ adj5 control\$ adj5 trial\$).mp.
11. (crossover or cross-over).mp.
12. ((singl\$ or double\$ or trebl\$ or tripl\$) adj (blind\$ or mask\$)).mp.
13. randomi\$.mp.
14. (random\$ adj5 (assign\$ or allocat\$ or assort\$ or receiv\$)).mp.
15. or/1-14
16. exp Schizophrenia/
17. exp Paranoid Disorders/
18. schizo\$.mp.
19. hebephreni\$.mp.
20. psychotic\$.mp.
21. psychosis.mp.
22. psychoses.mp.
23. ((chronic\$ or sever\$) adj2 mental\$ adj2 (ill\$ or disorder\$)).mp.
24. exp Bipolar Disorder/

25. or/16-24
26. 15 and 25
27. smoking cessation.mp. or exp Smoking Cessation/
28. "Tobacco-Use-Cessation"/
29. "Tobacco-Use-Disorder"/
30. Tobacco Smokeless.mp.
31. exp Tobacco Smoke Pollution/
32. exp Tobacco/
33. exp Nicotine/
34. exp Electronic Cigarettes/
35. ((quit\$ or stop\$ or ceas\$ or giv\$) adj5 smoking).ti,ab.
36. exp Smoking/pc, th [Prevention & Control, Therapy]
37. 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38. 26 and 37